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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,421	SACKSTEIN, ROBERT	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,65 and 71* is/are pending in the application.

4a) Of the above claim(s) *8-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission, filed on 07/10/2007, has been entered.

Applicant's amendment, filed 07/10/2007, has been entered.

Claims 1-4, 7 and 65 have been amended.

Claims 5-6 have been canceled previously.

Claims 1-4 and 71-65 are pending.

Claims 8-61 have been withdrawn as being drawn to non-elected inventions.

Claims 1-4, 7 and 62-65 are being acted upon as the elected invention. .

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's amendment, filed 07/10/2007.

The rejections of record can be found in the previous Office Action.

3. Priority:

As indicated previously,

Upon a review of USSN 60/240,987, the priority application USSN 60/240,987 does not support the broader claims of the instant application.

USSN 60/240,987 appears directed to the distinct glycoform of CD44 as an L-selectin ligand on human hemopoietic progenitor cells, namely HCLL-CD44, that is a 98 kD KG1a CD44 membrane protein and which may have 120 / 130 kD bands that reflect isoforms that were designated CD44R2 and CD44Ra, respectively (see entire document, including Results). This provisional application was directed to identifying an unknown/ unassigned adhesion molecule, which was shown to have a previously unrecognized function of a well-characterized adhesion molecule (e.g. see pages 4-5, overlapping paragraph of USSN 60/240,987).

The instant claims are broader in scope than the particular adhesion molecule HCLL-CD44 indentified and characterized in the priority document.

Further, it does not appear that priority USSN 60/240,987 provides sufficient written description for the claims nucleotide sequence comprising exons 1-5, 16, 18, and 20 of a human CD44 gene, wherein the CD44 polypeptide is a human CD44H, human CD44R1 or human CD44R2", "CD44 polypeptide comprises HECA-452 reactive sialyated, fucosylated N-glycans", wherein said glycosylated CD44 polypeptide is a ligand for both an E-selectin and L-selectin", and "wherein the preparation comprises less than 5% of a polypeptide other than the glycosylated CD44 polypeptide", as currently recited and as more broadly recited than previously described in USSN 60/240,987.

Also, it is noted that it does not appear that the priority USSN 60/240,987 provides sufficient written description for the limitations of the dependent claims, again as currently recited and more broadly recited than previously described in USSN 60/240,987.

Again, if applicant desires priority back to USSN 60/240,987, filed 10/18/2000; applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

A claim as a whole has only one effective filing date.

See e.g. Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant is reminded that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.

See Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

Therefore, the effective filing date of the instant claims are deemed to be the filing date of the provisional USSN 60/297,474, filed 06/11/2001.

4. Upon reconsideration of applicant's arguments in conjunction with the Sackstein Katz-type Declaration under 37 CFR 1.132 filed 07/10/2007,

the previous rejection under 35 U.S.C. § 102(a) as being anticipated by Dimitroff et al. (PNAS 97: 13841-13846, 2000) (1449; #AI) has been withdrawn.

5. Claims 1-4, 7 and 62-65 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sackstein et al. (Blood 89: 2773 – 2781, 1997), as further evidenced by Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) essentially for the reasons of record.

Applicant arguments in conjunction with the Sackstein Declaration under 37 CFR 1.132, filed 07/10/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

Again, applicant in conjunction with the Sackstein Declaration assert that no purified preparations of glycosylated CD44 polypeptides were described or isolated by Sackstein.

Applicant asserts that Figure 2 (or the discussion) does not show immunoprecipitation of HCELL/KG1 a CD44 in that the prior art Sackstein shows immunoprecipitation from radiolabeled KG1 a cell lysate which demonstrates that MECA-79 reactive polypeptides were not precipitated from KGla lysates whereas another polypeptide CD43 -- not CD44 was precipitated from the KGla lysates and that the other references cited by the Examiner as extrinsic evidence of anticipation, namely Dimitroff and Sackstein 2 do not change this fact.

In addition with respect to Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004), Sackstein as Declarant states that the prior art merely acknowledges that the identity of the backbone was a known polypeptide rather than some previously undiscovered polypeptide backbone. The statement was not intended to mean that the unique glycoprotein with a CD44 polypeptide backbone having a particular sialofucosylated carbohydrate structure that binds E-selectin or L- selectin and is reactive with monoclonal antibody HECA-452 was not novel as defined by United States Patent Law.

However, the inventor / author Sackstein does identify the HCELL / KG1a CD44 protein of the instant invention (see entire document, including the Abstract) as well as the immunoprecipitation of said HCELL / KG1a CD44 protein (see Results, including Figure 2 on page 2775 and Discussion) in the prior art rejection of record, namely Sackstein et al. (Blood 89: 2773 – 2781, 1997)

Therefore, the prior art is not limited to the asserted CD44 polypeptide backbone of the prior art.

Clearly, the prior art rejection of record Sackstein et al. (Blood 89: 2773 – 2781, 1997) describes and discusses the importance of sulfation in KG1a ligand, whether or not that the functional membrane glycoprotein L-selectin ligand whose binding activity was sulfate-dependent or not.

For example the Discussion, particularly page 2780, column 1 of the prior art Sackstein et al. reference notes:

The contribution of the sulfate modifications may relate to electrostatic forces via the localization of negative ions within discrete molecular determinants. Such a role for charge in L-selectin ligands is supported by the finding that unsulfated, but anionic polysaccharides such as polymers of phosphated mannose can bind to L-selectin. Within the KGla ligand, it is possible that glycosidic and/or amino acid modifications such as phosphorylation or the molecular composition of the discrete sugars or amino acids comprising the binding domain create a relevant anionic milieu. Present efforts are directed at isolating and characterizing the structure of this molecule. Although the pre cise structural features that direct binding activity for this and other naturally expressed membrane L-selectin ligands remain to be determined, the data presented here demonstrate that determinants conferring high-affinity recognition of L-selectin may vary among different cell types that express such ligands.

Also, note that the last line of the Abstract on page 2773 of 1 of the prior art Sackstein et al. reference states:

Identification of this novel ligand on non-endothelial cell type suggests that structural determinants conferring L-selectin binding may vary in a cell- and tissue-specific manner.

Again, it is the inventor Sackstein who teaches the hemopoietic cell L-selectin ligand which exhibits sulfate-independent binding activity that appears to be the same KG1a CD44 glycosylated polypeptide of the claimed invention (see entire document, including Abstract, Results and Discussion). Further, the Discussion describes the Results and the characterization of same KG1a CD44 isoform of the instant invention, including the nature of the sulfation-dependent epitope (see pages 2779-2780 of the Discussion)

Sackstein et al. teach the hemopoietic cell L-selectin ligand which exhibits sulfate-independent binding activity that appears to be the same KG1a CD44 glycosylated polypeptide of the claimed invention (see entire document, including Abstract, Results and Discussion).

Given the teachings including the Discussion of efforts to isolating and characterizing the structure of the KG1a ligand by Sackstein et al. at the time the invention,

one of ordinary skill would have immediately envisaged isolated HCELL / KG1a CD44 protein, including "isolated or purified protein that is substantially free of cellular materails or other contaminating protein from the cell or tissue source form which HCELL glycoprotein is derived or substantially freed form chemical precursors or other chemical when chemically synthesized , including being recombinantly produced, which is also free of culture medium (e.g. see page 11, paragraph 3 of the instant specification), thereby meeting the claimed limitation of "wherein the preparation comprises less that 5% of a polypeptide other than the glycosylated CD44 polypeptide".

As pointed out previously and in further evidence, Dimitroff et al. discloses that the L-selectin ligand disclosed in Sackstein et al. (Blood 89: 2773 – 2781, 1997) reads on the instant hemopoietic cell E- and L-selectin ligand (see reference 18 cited in the Introduction, particularly page 47623, column 2, paragraph 1).

Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) had been added as further evidence that the claimed HCLL is not novel or new.

"although initially considered to be a novel selectin ligand by the above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel per se: it is a glycoform of a well-recognized integral membrane glycoprotein, CD44, that expresses the CLA epitope."

See page 1064, column 1, paragraph 1 of Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Given the PTO's inability to manufacture products or to obtain and compare prior art products, the examiner properly shifted burden to applicant to establish, through objective evidence, that the very same KG1a CD44 polypeptide described by the inventor in by Sackstein et al. (Blood 89: 2773 – 2781, 1997), as well as by the inventor in the Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001). There is insufficient objective evidence that distinguishes the same or nearly the same KG1a CD44 isoforms in the prior art by the inventor from those CD44 isoforms currently encompassed by the instant claims.

Applicant's arguments have not been persuasive.

6. Claims 1-4, 7 and 62-65 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stamenkovic et al. (EMBO Journal 10: 343 –348, 1991) (see entire document, including Figure 1) as evidenced by Sackstein (US 2003/0040607 A1) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) essentially for the reasons of record.

Applicant arguments in conjunction with the Sackstein Declaration under 37 CFR 1.132, filed 07/10/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

With respect to the examiner's rebuttal with respect to the evidentiary references by Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004),

See Section 5 above for the applicability of these references in response to applicant's arguments.

Again, applicant in conjunction with the Sackstein Declaration assert that no purified preparations of glycosylated CD44 polypeptides were described or isolated by Sackstein.

For example, applicant in conjunction with the Sackstein Declaration submit that
Stamenkovic does not teach the isolation and source of native CD44 immunoprecipitated from hematopoietic cells
and points to Figure 3 of Stamenkovic et al., which demonstrates immunoprecipitation of the "hematopoietic form" of CD44 (CD44H) from CD44H transfected COS cells, wherein the the COS cell line is derived from kidney cells of the African Green monkey such that the CD44H-transfected COS cells cannot produce the claimed glycosylated polypeptide as COS cells are known to lack relevant fucosyltransferases (particularly fucosyltransferase VII), which are essential for producing the sialyfucosylated selectin binding determinants of the claimed glycosylated polypeptide
and that Figure 4 of Stamenkovic et al. demonstrates the immunoprecipitation of CD44 from carcinoma cell lines, which are the epithelial form and not the hematopoietic forms of CD44.

As indicated previously, Stamenkovic et al. teach the isolation and source of CD44, including immunoprecipitation of CD44 derived from hemopoietic cells (e.g., see The hematopoietic and epithelial CD44 isoforms show similar glysosaminoglcyan substitutions on page 345, column 2).

As indicated previously, applicant's arguments in conjunction with the Sackstein Declaration under 37 CFR 1.132, filed 07/27/2005, were fully considered but were not found convincing essentially for the reasons of record. Although applicant argues that the reference teaches only expression by those cells such as COS or Namalwa that would not express HCELL. The reference was not limited to expression by such cells.

In contrast to applicant's assertions, the prior art is not limited to certain examples and COS expression of CD44 isoforms, as the reference clearly teaches the isolation and immunoprecitipation of hemopoietic isoforms from their original hemopoietic cell sources.

Given the teachings including the teachings of isolating and characterizing as well as re-expression of each form of CD44 by Stamenkovic et al. at the time the invention,
one of ordinary skill would have immediately envisaged isolated hemopoietic CD44 isoforms from their original hemopoietic cell sources and not limited to the recombinant expression of said hemopoietic CD44 isoforms in COS cells only.

With respect to applicant's attention to the teachings of epithelial CD44 isoforms by Stamenkovic et al.,
as applicant acknowledges,
Stamenkovic et al. clearly teach the known hemopoietic CD44 isoforms at the time the invention was made.

Given the teachings including the teachings of isolating and characterizing as well as re-expression of each form of CD44 by Stamenkovic et al. at the time the invention, one of ordinary skill would have immediately envisaged isolated HCELL / KG1a CD44 protein, including "isolated or purified protein that is substantially free of cellular materails or other contaminating protein from the cell or tissue source form which HCELL glycoprotein is derived or substantially freed form chemical precursors or other chemical when chemically synthesized , including being recombinantly produced, which is also free of culture medium (e.g. see page 11, paragraph 3 of the instant specification), thereby meeting the claimed limitation of "wherein the preparation comprises less that 5% of a polypeptide other than the glycosylated CD44 polypeptide".

Stamenkovic et al. teach the expression of CD44 transcripts in primary tumors of mesenchymal and epithelial origin, in normal epithelium and in lymphocytes (see page 344, column 1, paragraph 1 and Figure 2 as well as pages 345-346).

Also, Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) has been added as further evidence that the claimed HCLL is not novel or new.

"although initially considered to be a novel selectin ligand by the above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel per se: it is a glycoform of a well-recognized integral membrane glycoprotein, CD44, that expresses the CLA epitope."

See page 1064, column 1, paragraph 1 of Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Therefore, as pointed out previously and in contrast to applicant's assertions, Stamenkovic et al. teach hemopoietic and epithelial forms of CD44, including encoding nucleotide and amino acids of CD44, which appear to be the same or nearly the same as the instant hemopoietic cell L-selectin / E-selectin ligand (HCELL), also referenced to as KG1a CD44, which is a glycoform of CD44 and comprising SEQ ID NO: 1, as set forth in Sackstein (US 2003/0040607 A1; see entire document, including Summary of the Invention, Examples, Table 1 and Claims).

Given the teaching of the structural characterization (e.g. amino acid and encoding nucleic acids) of CD44 isoforms as well as hemopoietic source of said CD44 isoforms (e.g CD44H referenced in Stamenkovic et al.) which is consistent with the instant disclosure as well as applicant's publication Sackstein (US 2003/0040607 A1) as well as the breadth of the instant claims, the prior art appears to read on the claimed polypeptides, in the absence of objective evidence to the contrary.

As indicated previously,

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

As set forth in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999): "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

The PTO's inability to manufacture products or to obtain and compare prior art products. Examiner properly shifted burden to applicant to establish, through objective evidence, that the very same KG1a CD44 polypeptides, including hemopoietic derived CD44 isoforms comprising SEQ ID NO: 1 described by Stamenkovic et al. and consistent with the teachings of the instant application and inventor's publication Sackstein (US 2003/0040607 A1), currently encompassed by the instant claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(C).

Applicant's arguments are not found persuasive.

7. This is a New Grounds of Rejection.

Claims 1-4, 7 and 62-65 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dougherty et al. (J. Exp. Med. 174: 1-5, 1991) (1449; #AJ) (see entire document) as further evidenced by Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) essentially for the reasons of record.

Dougherty et al. teach the isolation and molecular cloning of CD44R1 and CD44R2, as well as their expression on various hemopoietic cells and cell lines, including the KG1a cell lines.

Given the teaching of the structural characterization (e.g. amino acid and encoding nucleic acids) of CD44R1 and CD44R2 isoforms as well as hemopoietic source of said CD44R1 and CD44R2 isoforms, which is consistent with the instant disclosure as well as instant claims 62-64 as well as the breadth of the instant claims, the prior art appears to read on the claimed polypeptides, in the absence of objective evidence to the contrary.

With respect to the examiner's rebuttal with respect to the evidentiary references by Dimitroff et al. (J. Biol. Chem. 276: 47623 – 47631, 2001) and Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004),
See Section 5 above for the applicability of these references as well as the rebuttal in response to applicant's arguments.

Also, Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004) has been added as further evidence that the claimed HCLL is not novel or new.
"although initially considered to be a novel selectin ligand by the above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel per se: it is a glycoform of a well-recognized integral membrane glycoprotein, CD44, that expresses the CLA epitope."
See page 1064, column 1, paragraph 1 of Sackstein (J. Invest. Dermatol. 122: 1061-1069, 2004).

Therefore, as pointed out previously and in contrast to applicant's assertions, Stamenkovic et al. teach hemopoietic and epithelial forms of CD44, including encoding nucleotide and amino acids of CD44, which appear to be the same or nearly the same as the instant hemopoietic cell L-selectin / E-selectin ligand (HCELL), also referenced to as KG1a CD44, which is a glycoform of CD44 and comprising SEQ ID NO: 1, as set forth in Sackstein (US 2003/0040607 A1; see entire document, including Summary of the Invention, Examples, Table 1 and Claims).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

As set forth in Atlas Powder Co. V: IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999): "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Given the PTO's inability to manufacture products or to obtain and compare prior art products, the burden has been shifted to applicant to establish, through objective evidence, that claimed CD44 polypeptides are distinguishable from the very same or nearly the same KG1a CD44 polypeptides, including hemopoietic derived CD44H, CD44R1 and CD44R2 isoforms described by the prior art are607 A1), currently encompassed by the instant claims.

8. Claims 1-4, 7 and 62-65 are rejected under 35 U.S.C. § 103(a) as being unpatentable
over Sackstein et al. (Blood 89: 2773 – 2781, 1997) (of record)
AND / OR Stamenkovic et al. (EMBO Journal 10: 343 –348, 1991) (of record)
AND / OR Dougherty et al. (J. Exp. Med. 174: 1-5, 1991) (1449; #AJ)
in view of art known and practiced procedures to isolate and express isolated or purified proteins of interest at the time the invention was made,
as taught by Ni et al. (U.S. Patent No. 5,942,417) (892; of record),
as as taught by McEver et al. (U.S. Patent No. 6,124,267)
and as acknowledged on pages 19-24 of the instant specification and as evidenced by the following statements in the instant specification that it would be appreciated by those skilled in the art that the design of the expression vector can depend on such factors as the choice of the host cell to be transformed, the level of expression of protein desired.

Applicant arguments in conjunction with the Sackstein Declaration under 37 CFR 1.132, filed 07/10/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal with respect to the teachings of Sackstein et al. (Blood 89: 2773 – 2781, 1997) and Stamenkovic et al. (EMBO Journal 10: 343 –348, 1991) have been addressed above.

While this is a New Grounds of Rejection, it is noted that Dougherty et al. (J. Exp. Med. 174: 1-5, 1991) (1449; #AJ) as well as McEver et al. (U.S. Patent No. 6,124,267) as well as applicant's acknowledgement in the instant specification that it would be appreciated by those skilled in the art that the design of the expression vector can depend on such factors as the choice of the host cell to be transformed, the level of expression of protein desired.

The teachings of Sackstein et al. and Stamenkovic et al. are set forth above and are of record in the rejection under 35 U.S.C. § 103(a) of record.

As indicated above
Dougherty et al. teach the isolation and molecular cloning of CD44R1 and CD44R2, as well as their expression on various hemopoietic cells and cell lines, including the KG1a cell lines.
Given the teaching of the structural characterization (e.g. amino acid and encoding nucleic acids) of CD44R1 and CD44R2 isoforms as well as hemopoietic source of said CD44R1 and CD44R2 isoforms, which is consistent with the instant disclosure as well as instant claims 62-64 as well as the breadth of the instant claims, the prior art appears to read on the claimed polypeptides, in the absence of objective evidence to the contrary.
Dougherty et al. differs from the claimed invention by not being explicit in terms of certain structural or functional characteristics as currently claimed.

Sackstein et al., Stamenkovic et al. and Dougherty et al. differ fom the claimed invention by not disclosing the purity of their referenced CD44 glycoforms or that they do not exemplify the isolation of their referenced CD44 glycoforms via known and practiced recombinant methods to isolate and express proteins of interest by the ordinary artisan at the time the invention was made.

Ni et al. teach the known and practiced methods of isolating and expressing isolated proteins of interest, including its application to CD44 proteins at the time the invention was made (see entire document, including Summary of the Invention, Detailed Description and Examples). Also, note that Ni et al. teach that isolated encompasses removed from its native environment, purified and produced by recombinant means (e.g. see column 18, paragraph 1).

McEver et al. teach the known manipulation and expression of proteins of interest that are associated with sialylated and fucosylated glycans and that interact with selectins, including the use of fucosyltransferases in the expression and anyalysis of said proteins of interest at the time the invention was made (see entire document, including Detailed Description of the Invention, including Expression Systems on columns 9-11 and Examples on columns 15-44).

Consistent with the prior art of record and newly added McEver et al.,
Pages 19-24 of the instant specification acknowledges the art known and practiced procedures to isolate and express isolated or purified proteins of interest at the time the invention was made.
For example, page 20, paragraph 2 of the instant specification states that
It would be appreciated by those skilled in the art that the design of the expression vector can depend on such factors as the choice of the host cell to be transformed, the level of expression of protein desired.
In this Section on HCELL Recombinant Expression Vectors and Host Cells,
It is noted that applicant also relies upon prokaryotic and eukaryotic cells, including CHO or COS cells, as well as tissue-specific regulatory elements known and practiced at the time the invention was made.

Given the teachings of Sackstein et al., Stamenkovic et al. and Dougherty concerning the expression and role of the claimed CD44 glycoforms, one of ordinary skill in the art would have isolated and produced CD44 glycoforms via various known means at the time the invention was made, including recombinant means as a standard practice to investigate the role and use of said CD44 glycoforms in physiological events. Given the standard practices of isolating and recombinantly expressing antigens, including adhesion molecules such as CD44 glycoforms as well as the known manipulation and expression of proteins of interest that are associated with sialylated and fucosylated glycans and that interact with selectins, including the use of fucosyltransferases in the expression and anyalysis of said proteins of interest at the time the invention was made, one of ordinary skill in the art had a reasonable expectation of success in preparing the claimed CD44 glycoform in preparation comprising less than 5% of the CD44 glycoform other than the glycosylated CD44 polypeptide. The advantages of isolated and purified molecules of interest, including adhesion molecules as CD44 glycoforms, were well known and practiced in the art at the time the invention was made in order to study and characterize the molecule / protein of interest for structure-function relationships as well as to employ such proteins for a wide variety of utilities associated with the molecule / protein of interest. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments as they read on this New Grounds of Rejection have not been found persuasive.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable
over claims 1-18 and 77-78 of copending USSN 11/272,453 and
over claims 1-4 of copending USSN 11/032,256.

The instant and copending claims appear to be drawn to the same or nearly the same CD44 glycosylated isoforms, including HCELL. Therefore, the copending claims and the instant claims appear to anticipate or render obvious one another.

11. It is noted that applicant has a number of copending applications drawn to CD44 glycosyalte isoforms, particularly to those associated with HCELL.

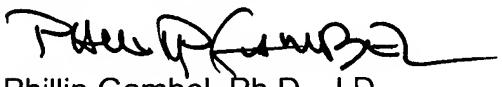
Applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

12. No claim allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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